

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT DELAWARE**

INGENUS PHARMACEUTICALS, LLC,
and LEIUTIS PHARMACEUTICALS LLP,

Plaintiffs,

v.

ACCORD HEALTHCARE, INC. and
INTAS PHARMACEUTICALS LTD.,

Defendants.

Case No. 1:23-cv-00377-JLH

PUBLIC VERSION

**LETTER TO THE HONORABLE JENNIFER L. HALL CONCERNING
DEFENDANTS' MOTION TO STRIKE PORTIONS OF THE
EXPERT REPORT OF STEPHEN HOLZEN**

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Dear Judge Hall:

Accord moves to strike the expert opinions of Mr. Holzen related to theories of commercial success, sales and market share, and licensing never disclosed during fact discovery and relying on belatedly produced documents. Ingenus' unexplained delay has inhibited Accord's ability to take factual discovery on these matters and properly prepare a response. As such, those opinions (Ex. A at ¶¶33-49, 51-60, 69) should be stricken.

Background. Throughout discovery, Accord sought to ascertain which objective indicia of non-obviousness Ingenus was asserting, most notably in Interrogatory No. 6. (Ex. B at pg. 4.) Accord further served requests for production relating to objective indicia of non-obviousness, including RFP No. 16. (Ex. C at pg. 20.) Initially, Ingenus responded that it would provide its response at the appropriate time. (*See* Ex. B at pg. 5.) For months, Ingenus did not supplement its response, despite repeated requests by Accord. (*See* Ex. D at pg. 1-2.)

Ingenus provided no substantive response until July 13, 2024 when it identified only that it “expect[s] to rely on at least copying and long-felt need.” (Ex. B at pg. 5.) Ingenus did not identify commercial success, sales and market share, or licensing theories. (*See Id.* at 4-6.) Instead, Ingenus specifically disclosed that its ready-to-use (RTU) formulation solved a need that existed with previous powder formulations of cyclophosphamide, including long preparation times and contamination/dosing issues, which were due to the reconstitution step when using a powder formulation in an IV injection. (*Id.* at 5-6.) Fact discovery closed on July 31, 2024. Notwithstanding its failure to supplement its discovery responses, Ingenus undertook the following activities after the close of fact discovery: (1) 9/15/2024 – identified Mr. Holzen as a financial consultant; (2) 9/20/2024 – produced a summary of financial details for its product (*see* Ex. E at pgs. 2-3); and (3) 10/29/2024 – produced a summary of the July 2024 market. (*See* Ex. F.) Yet, Ingenus did not supplement its Interrogatory No. 6 Response on any of these dates.

In response to this late-produced financial information, Accord reminded Ingenus that it had not disclosed any relevant theory for such financial information and advised Ingenus that Accord would move to strike any attempt to insert such information into the litigation. (*See* Ex. E at pg. 1.) Accord invited Ingenus to address the matter at that time, but Ingenus refused. (*Id.*)

On December 9, 2024, Ingenus served Mr. Holzen's report, which provided opinions regarding objective indicia of non-obviousness for the '952 patent, based on the licensing and sales of Ingenus' RTU product. (Ex. A at ¶¶33-68.) Although Mr. Holzen fashioned his opinions as relevant to “long felt, but unmet need,” his report discusses the licensing activities for Ingenus' RTU product (*id.* at ¶¶34-51) and its sales and market share (*id.* at ¶¶52-61) and not the long-felt need theory disclosed in Ingenus' interrogatory response. Accord met and conferred with Ingenus on December 13, 2024. Unable to reach a compromise regarding the new theories presented by Mr. Holzen, Accord submits this instant motion.¹

Legal Standard. A party that fails to comply with Rule 26(a) or (e) “is not allowed to use that

¹ Ingenus offered further discovery to Accord. But as Accord explained to Ingenus and in this motion, to fairly respond to Ingenus' untimely theories, Accord needs discovery not only from Ingenus, but from third parties in the market.

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information or witness to supply evidence ... unless the failure was substantially justified or harmless.” Fed. R. Civ. P. 37(c)(1). The Third Circuit considers the *Pennypack* factors when determining whether exclusion is appropriate: (1) the prejudice or surprise to the moving party; (2) the ability of that party to cure the prejudice; (3) disruption to trial of the case or of other cases in the court; (4) bad faith or willfulness; and (5) importance of the information withheld. *See Meyers v. Pennypack Woods Home Ownership Assn.*, 559 F.2d 894, 903-04 (3d Cir. 1977).

Argument. Ingenus’ late disclosure is neither justified nor harmless, and thus, the Court should strike the portions of Mr. Holzen’s report advancing these new theories.

Prejudice and Surprise to Accord. Accord is surprised by Ingenus’ new theories, which were never disclosed. Although Mr. Holzen fashioned his opinions as related to “long-felt but unmet needs,” Ingenus’ response to Interrogatory No. 6 did not address any commercial success, sales and market share, or licensing theories (*Id.*), which are distinct objective indicia from long-felt need, *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 711 F.3d 1348, 1368 (Fed. Cir. 2013), or otherwise address sales and licensing as indicative of any long-felt need.

Accord is also highly prejudiced by Ingenus’ late disclosure as it has been deprived of the opportunity to evaluate Ingenus’ theories through fact discovery. Based on Ingenus’ representations that it was relying only on copying and long-felt but unmet need, Accord did not take discovery related to commercial success, sales and market share, or licensing. As such, this factor strongly favors exclusion. *See NexStep, Inc. v. Comcast Cable Communs., LLC*, 2021 WL 5356293, at *3 (D. Del. Nov. 17, 2021) (“[a]llowing the new theory [during expert discovery] would have [foreclosed] targeted discovery around the factual basis of the theory.”); *Semcon IP Inc. v. MediaTek Inc.*, 2018 WL 4501871, at *5 (E.D. Tex. Feb. 28, 2018).

No Possibility to Cure Prejudice Without Disruption to Case Schedule. At this point, there is no possibility to cure prejudice caused by Ingenus. The parties have already completed expert reports, expert discovery closes January 17, 2025, *Daubert* motions are due on January 24, 2025, and trial is scheduled for March 24, 2025. No time is left to adequately cure the prejudice caused by Ingenus, which cannot be cured solely through expert discovery alone. *See NexStep*, 2021 WL 5356293, at *3 (acknowledging that “[i]t is irrelevant that Comcast could have asked [the non-moving party’s expert] pertinent questions at his deposition.”); *Semcon IP*, 2018 WL at *5.

With trial only three months away, Accord will not have the sufficient time to take third-party discovery to test Mr. Holzen’s licensing theories. For example, Mr. Holzen suggests that third parties, such as Athenex and Dr. Reddy’s, “could have marketed and sold [their] own liquid cyclophosphamide product in the United States, but chose not to do so” and instead licensed Ingenus’ product. (*See, e.g.*, Ex. A at ¶¶38, 45, 51.) Accord would need discovery directly from Dr. Reddy’s and Athenex to test Mr. Holzen’s opinions including whether they had developed alternate products and their reasons for licensing with Ingenus.

Further, Accord will not have time to take discovery to test Mr. Holzen’s commercial success or sales and market share theories. Namely, Mr. Holzen points to Ingenus’ large share of the market relative to formulations sold by Bluepoint and Eugia (and compared to powdered formulations sold by unnamed parties, *e.g.*, Baxter). Accord would require discovery from Bluepoint and Eugia, as well as the broader market selling powdered formulations to validate such claims and assess

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whether the relative sales are due to technical aspects of the product or due to, for example, marketing position. Further, Accord would need discovery on sales data outside of the cherry-picked document produced by Ingenus, marketing/advertising documents from third parties², competitive analysis documents, consumer demand documents, and insurance-related documents. Such discovery cannot be completed with trial only three months away. *See Semcon IP*, 2018 WL at *5 (striking rebuttal on secondary considerations that “left [moving party] without an adequate means to develop a response, including any response that would require discovery.”)

Without striking Mr. Holzen’s untimely opinions, the case schedule would be unjustifiably disrupted. As explained above, trial is just 3 months away. It would be unfair to Accord and the Court to extend the case schedule, given the expiration of the 30-month stay (August 25, 2025) or would otherwise require the parties and Court to proceed on a significantly expedited schedule. Neither Accord, nor the Court, should have to take that risk because of Ingenus’ late disclosure.

Ingenus Was Willful & Acted in Bad Faith. Accord repeatedly requested Ingenus’ objective indicia theories, which Ingenus did not identify until rebuttal reports. Accord even invited Ingenus to address this dispute two months ago, but Ingenus called Accord’s invitation “premature.” (Ex. E, at pg. 1.) Ingenus’ conduct was thus at least approaching willful and bad faith. Further, Ingenus undoubtedly had its own sales data throughout the entirety of this litigation, which favors exclusion. *See TwinStrand Biosciences, Inc. v. Guardant Health, Inc.*, C.A. No. 21-1126, D.I. 467, at *1 (D. Del. Oct. 31, 2023) (oral order) (even if not “bad faith” fact that “Plaintiffs could have, but chose not to, disclose their DOE theories” favored exclusion); *see also Baptiste v. Rohn*, 2016 WL 1060237, at *6 (D.V.I. Mar. 15, 2016) (“Plaintiff’s conduct was particularly egregious given that the contact information sought was admittedly in her possession. Thus, the bad faith factor favors exclusion of the testimony at issue here”).

Excluded Portions Are Not So Important as to Justify Late Disclosure. Ingenus has retained another expert to opine on long-felt need, which opinion aligns with the theories that Ingenus disclosed during fact discovery. (*See generally*, Ex. G (Expert Report of Mr. Zamboni).) As such, this factor weighs in favor of exclusion or is at worst neutral.

Conclusion. Ingenus’ late disclosure of its commercial success, sales and market share, and licensing theories was neither justified nor harmless. Accord’s motion to strike should be granted. *See Semcon IP*, 2018 WL 4501871, at *5 (granting motion to strike because “[a]lthough secondary considerations may be important, the prejudice to MediaTek is significant, particularly because Semcon did not disclose the facts it already had knowledge of upon which it would rely. Dr. Carbonell’s rebuttal opinion regarding secondary considerations therefore left MediaTek without an adequate means to develop a response, including any response that would require discovery.”).

² Specifically, Mr. Holzen claims that “Ingenus relied upon Athenex for marketing[.]” (*Id.* at ¶49.) The evidence of the actual “marketing and advertising efforts” would require discovery in the possession of Athenex to rebut nexus. *See In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2008) (evidence may show sales were not “a direct result of the unique characteristics of the claimed invention” but rather the “effectiveness of the marketing efforts employed.”); *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1067 (Fed. Cir. 2020) (noting if plaintiff is entitled to a presumption of nexus, defendant must introduce evidence rebutting that presumption).

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Respectfully,

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